## ART 34 AMDT 09/623181

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## **Claims**

- 1. An assay device (19) having at least one chamber (14) in fluid connection with at least one pathway (14/a, 14/b), the pathway being adapted to allow fluid to flow to/from said chamber (14), characterised in that there is provided a volume of deformable material (46) in the pathway (14), which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway.
- 2. An assay device (16) having at least one chamber (15) in fluid connection with at least one pathway (144, 146) the pathway being adapted to allow fluid to flow to/from said chamber (14) characterised in that there is at least one recess located substantially adjacent the pathway and, situated in the recess, there is provided a volume of deformable material (44) which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway.
- am 1 wherein there is at least one recess located 3. An assay device (10) according to substantially adjacent the pathway
- Claim An assay device (16) according to any of claims 1 to 3 wherein an opening is provided, the opening acting as a vent to or from the recess.
- An assay device (10) according to claim wherein the deformable material (40) is situated in the pathway (14b) such that the pathway is partially obstructed.
- 6. An assay device (10) according to any of claims 1 to 5 wherein the chamber (38,49) comprises a deformable envelope and at least two points of the envelope are connected by way of a volume of deformable material (48,56).
- Claim 7. An assay device (19) according to any of claims 1-to-6 wherein a region of the device has at least one hydrophobic portion so that the flow of the deformable material is guided along a predeter/nined/pa
- Chim claims 1 to 7 wherein the deformable material is ording 8. An assay device (19) ac thermally deformable.
- 9. An assay device (10) according to any of claims 1 to 7 wherein the deformable material is mechanically deformable.

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- 10. An assay device (10) according to any of claims 1 to 9 further including heating means (80).
- 11. An assay device (10) according to any of claims 1 to 10 further including a means for removing heat.
- 12. An assay device (10) according to any of claims 1 to 11 wherein the at least one surface defined by or in the device is resiliently deformable.
- 13. An assay device (10) according to any of claims to 12 wherein a plurality of volumes of deformable material are provided, each volume being accessible independently one from another.
- 14. An assay device (10) according to any of claims 1 to 13 having at least one component from the set of: an inlet port (12), a reaction chamber (14), a waste depot (16), a filter chamber (18), an infinity capture and processing chamber (20), a wash solution/reagent reservoir (22), an array of metered readout cells (26,28,30,32), and a breather tube (11, 13).
- 15. An assay device (10) according to the of claims 1 to 14, in which heat is selectively applied to one or more of the volumes of the deformable material.
- 16. An assay device (10) according to any of claims 1 to 15, in which heat is selectively removed from one or more volumes of the deformable material.
- 17. An assay device (19) according to any of claims 1 to 16, in which pressure is selectively applied to at least one region contained within the device.
- 18. An assay device (10) having: a) at least one chamber (14) in fluid connection with at least one pathway (14a, 14b), the at least one pathway being adapted to allow fluid to flow to/from said at least one chamber (14); b) a volume of deformable material (46) situated in the pathway (14b) which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway; and c) at least one hydrophobic portion which defines a path along which the deformable material is guided.

- 19. An assay device (10) having: a) at least one chamber (14) in fluid connection with at least one pathway (14a, 14b), the at least one pathway being adapted to allow fluid to fl w to/from said at least one chamber (14); b) at least one recess located substantially adjacent the pathway; c) a volume of deformable material (44) situated in the recess which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway; and d) at least one hydrophobic portion which defines a path along which the deformable material is guided.
- 20. A method of manufacturing the assay device (10) of any of claims 1 to 19, including the steps of: a) defining at least one fluid pathway (14a) on a substrate; b) defining at least one reaction chamber (14) on a substrate; c) forming at least one component composed of a deformable material (44) in the device; and d) bonding together at least two substrates to form the device (10).
- 21. A method of manufacturing the device (10) according to claim 20, wherein the at least one fluid pathway (14a) may be formed by: a) printing, b) etching, c) ablation, d) use of a mould, e) cutting, or a combination of any of steps/a) to e).
- 22. A method of manufacturing the device (10) according to claim 20, wherein the at least one reaction chamber (14) is formed by: a) printing, b) etching, c) ablation, d) use of a mould, e) cutting, or a combination of any of steps a) to e).
- 23. A method of manufacturing the device (10) according to claim 20, wherein the at least one component (44) composed of a deformable material is formed by: a) printing of the deformable material onto the substrate, b) etching, c) pick-and-placing of components, d) injection of molten material into device using feeder tubes, or a combination of steps a) to d).
- 24. A method of manufacturing the device (10) according to claim 20, wherein the at least one substrate is bonded by: a adhesives, b) curing, c) mechanical fixing, d) heating, e) anodic bonding, or a combination of steps a) to e).
- 25. Apparatus for varying the rate of fluid flow along a pathway (75), the apparatus including at least one pathway (75) and a volume of deformable material (78) disposed within the pathway whereby, in use, a change of state of the deformable material causes a change of the rate of fluid flow along the pathway.

- 26. Apparatus for varying the rate of fluid flow along a pathway (75), the apparatus including at least one pathway (75) and a volume of deformable material (78) disposed adjacent the pathway whereby, in use, a change of state of the deformable material causes a change of the rate of fluid flow along the pathway.
- 27. Apparatus according to claim 25 or 26 further including at least one chamber in fluid connection with the pathway.
- 28. Apparatus according to claim 27 wherein a volume of deformable material is disposed within the chamber.
- 29. Apparatus according to any of claims 25 to 28 wherein at least one recess (72) capable of receiving deformable material is located substantially adjacent the pathway (75).
- 30. Apparatus according to claim 29 wherein the at least one recess (72) has an opening (74) which acts as a vent in order to permit the flow of gas therethrough.
- 31. Apparatus according to any of claims 25 to 30 including at least one hydrophobic region (76) in order to guide fluid along a predetermined path.
- 32. Apparatus according to any of claims 25 to 31 including means for the supply and/or removal of heat from the apparatus in order to increase or decrease the rate of change of state of the deformable material.
- 33. Apparatus according to any of claims 25 to 32 including means for the supply of (i) pressure, (ii) uv radiation, (iii) light, (iv) ultrasonic energy or a combination of any of (i) to (iv) to the apparatus in order to change the state of the deformable material.
- 34. Apparatus according to any of claims 25 to 33 wherein the deformable material (78) includes a polymer.
- 35. Apparatus according to any of claims 25 to 33 wherein the deformable material (78) includes polypropylene polystyrene
- 36. Apparatus according to any of claims 25 to 30 including at least one hydrophobic portion (76) which defines a path along which deformable material is guided.

- 37. Apparatus for varying the rate of fluid flow along a pathway (75), the apparatus including: a) at least one pathway (75); b) a volume of deformable material (78) disposed within the pathway, which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway; and c) at least one hydrophobic region (7,6) which defines a path along which deformable material is guided.
- 38. Apparatus for varying the rate of fluid flow along a pathway (75), the apparatus including: a) at least one pathway (75), b) a volume of deformable material (78) disposed adjacent the pathway, which, in use, change its state so as to cause a change of the rate of fluid flow along a pathway; and c) at least one hydrophobic region (76) which defines a path along which deformable material is guided.
- 39. A method of varying the rate of fluid flow along a pathway (75) comprising the steps of: providing at least one recess (72) located substantially adjacent the pathway (75); locating a plug of deformable material (78) in the pathway so that the material substantially restricts the flow of fluid in the pathway; and changing the state of the deformable material so that at least a portion of the material passes into the at least one recess thereby permitting flow of the fluid along the pathway/
- 40. A method of varying the rate of fluid flow along a pathway comprising the steps of: providing at least one recess (72) located/substantially adjacent the pathway (75), locating a volume of deformable material (78) in the at least one recess; and changing the state of the deformable material so that at least a portion of the material passes into the pathway thereby substantially restricting flow/of the fluid along the pathway.
- 41. A method of varying the rate of fluid flow along a pathway (78) comprising the steps of: providing a pathway (7,5); locating a volume of deformable material (78) in the pathway so that it substantially restricts the flow of fluid along the pathway (75), and changing the state of the deformable material so that at least a portion of the material (78) passes along a predetermined path thereby permitting flow of the fluid along the pathway.
- 42. A method of varying the rate of fluid flow along a pathway (75) comprising the steps of: providing a pathway (75); locating a volume of deformable material (78) in the pathway so that it substantially permits the flow of fluid along the pathway; and changing the state of the deformable material so that at least a portion of the material (78) passes along a predetermined path thereby substantially r stricting flow of the fluid along the pathway.

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- 43. A method according to claim 41 or claim 42 wherein the predetermined path is defined by one or more hydrophobic regions (76).
- 44. A method according to claims 39 to 42 whereby the state of the deformable material (78) is changed by applying to said material (i) heat, (ii) pressure, (iii) uv radiation, (iv) light, (v) ultrasonic energy or a combination of any of (i) to (v).
- 45. A method of varying the rate of fluid flow along a pathway (75) comprising the steps of: providing at least one recess (72) located substantially adjacent the pathway (75); locating a plug of deformable material (78) in the pathway/so that the material substantially restricts fluid flow in the pathway; and changing the state of the deformable material so that at least a portion of the material passes along a predetermined path into the at least one recess thereby permitting flow of the fluid along the pathway, wherein the predetermined path is defined by one more hydrophobic regions.
- 46. A method of varying the rate of fluid flow along a pathway comprising the steps of: providing at least one recess (72) located substantially adjacent the pathway (75); locating a volume of deformable material (78) in the at least one recess; and changing the state of the deformable material so that at least a portion of the material passes along a predetermined path into the pathway thereby substantially restricting flow of the fluid along the pathway, wherein the predetermined path is defined by one or more hydrophobic regions.
- 47. A method of varying the rate of fluid flow along a pathway (75) comprising the steps of: providing a pathway (75); locating a volume of deformable material (78) in the pathway so that it substantially restricts fluid flow along the pathway (75), and changing the state of the deformable material so that at least a portion of the material (78) passes along a predetermined path thereby permitting flow of the fluid along the pathway, wherein the predetermined path is defined by one or more hydrophobic regions.
- 48. A method of varying the rafe of fluid flow along a first pathway (75) comprising the steps of: providing a first pathway (75) locating a volume of deformable material (78) in the first pathway; flowing a fluid along the first pathway past the material; and changing the state of the material so that at least a portion of the material (78) passes along a second pathway so as to restrict fluid flow along the first pathway, said second pathway being defined by one or more hydrophobic regions.

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- 49. An assay device (10) substantially as described with reference to Figure 1.
- 50. Apparatus substantially as described herein with reference to Figures 2 to 9.
- 51.A method of varying the rate of fluid flow along a pathway substantially as described herein with reference to the Figures.
- 52. A method of performing chemical analysis substantially as described with reference to the Figures.